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an integrally formed cap closing said ampoule, said cap located at a score line on said ampoule to facilitate removal, said score line on said ampoule, once exposed by removal of said cap, dimensioned to receive a luer coupling thereat, and walls of said ampoule formed of deformable flexible non-porous material.

REMARKS

The Office Action dated April 9, 2002, has been received and its contents carefully noted. With respect to the requirement for election and restriction between groups I through IV, applicant hereby provisionally elects group III, consisting of claims 24 through 38 and 41 through 47. Applicant traverses the election requirement of all groups for a multiplicity of reasons.

It is believed that the non-elected claims, 1 through 23, 39, and 40 are so closely related to the elected claims that they should remain in the same application to preserve unity of the invention and thus avoid any possibility of the charge of double patenting arising at some later date. All of the above-identified claims are broadly directed to a lyophilisate delivery method and apparatus. Essentially, an ampoule contains lyophilized material which is subsequently hydrated. The statutory requirement under 35 U.S.C. §121 that there be both independence and distinction between the inventions has not been met. It has not been shown why the claims should be considered independently as required by the language of §121 and 37 C.F.R. §1.141(b). The Examiner has not set forth with specificity in the last Office Action what he believes the distinction to be between the method of making an ampoule with the lyophilized material, of using the ampoule and its operating environment. Therefore, this restriction requirement should be withdrawn.

More particularly, the Examiner generally asserts that groups I, II, III, and IV are distinct inventions. However, undersigned points out the following additional requirements that the Examiner must meet to compel a restriction. In particular, MPEP §803 requires that there must also be a serious burden on the Examiner if restriction is required. Undersigned does not see any enunciation of such burden in the Examiner's restriction requirement. The Examiner had only contended that the inventions of groups I, II, III, and IV are distinct from each other because they are related 1) as apparatus and product made and 2) as process of making and product made. The Examiner generally asserts that the product as claimed can be made or used with a different method and vice versa.

Furthermore, it is undersigned's contention that, to the contrary, the burden would be greater on the Examiner if restriction is required. That is, as all of the claims are closely related, solving the same problem, certain efficiencies would be achieved by the Examiner examining both groups simultaneously. Splitting the examination, as the Examiner is now requiring, will actually double this or another Examiner's work in the long run.

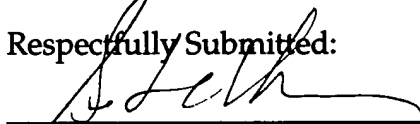
For all of the foregoing reasons, the Examiner is respectfully requested to withdraw the restriction requirement between groups I, II, III, and IV. Claims 1 through 24 constituting groups I and II have not been provisionally elected. Claims 39 and 40 of group IV are also not elected. (As mentioned supra, claims 41-47 have been erroneously grouped in group IV by the Examiner but belong in group III.) Applicant still reserves the right to file a divisional application for this subject matter and does not waive any right therefore or abandon such subject matter.

A Preliminary Amendment is also provided before receipt of any substantive Office Action on the merits of this case. One new claim is before the Examiner which makes manifest the connection between the needleless dosage transfer system and the ampoule of the present invention.

In view of the foregoing, the Examiner is respectfully requested to reconsider the position taken in the last Office Action acting favorably hereon by removing this restriction requirement. If, upon further consideration, the Examiner believes that further issues remain outstanding or new ones have been generated, the Examiner is respectfully requested to call undersigned in order to expeditiously resolve same.

Dated: May 9, 2002

Respectfully Submitted:



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